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SYSTEM AND METHOD FOR TRANSMITTING ENERGY TO AND ESTABLISHING A COMMUNICATIONS NETWORK WITH ONE OR MORE IMPLANTED DEVICES

Technical Field

The present device relates generally to implantable medical devices and particularly, but not by way of limitation, to an external device that can provide energy to and communicate with the implantable device or a network of such devices through inductive and/or telemetric coupling.

Background

Implantable devices are indicated for an increasing number of patients and an increasing variety of medical conditions. Fully implantable systems are preferred to avoid the need to carry and maintain an external power source, which is inconvenient to the patient and serves as a constant source of worry because the patient is continuously aware of the device. However, fully implantable systems often place design constraints on the power consumption of the device due to the competing objectives of high device longevity versus device compactness.

The use of inductive power coupling of implantable medical devices to help solve this power/size dichotomy is well known. For example, inductive power coupling has been utilized in LVAD (artificial hearts), cochlear implants and respiratory pacemakers.

Inductive power links are of two main types – tightly coupled links versus loosely coupled links. Tightly coupled links are typically characterized by known or close distances between the transmission and reception components. In addition, the geometry of tightly coupled links is typically known or fixed. In contrast, loosely coupled systems operate over variable distances and with unknown or variable geometric orientations. However, loosely coupled systems are typically characterized by low power transmission efficiencies.

Systems to transmit power across a variable coupling distance of 4-8 cm have been demonstrated to attain a transmission efficiency of about 10%. *See* Benedetti, R. et al., *Overview of Telemetry Systems With Inductive Links and Variable Coupling Distances*, International Conference on Biotelemetry XIII, March 1995, which is incorporated herein by reference. Systems of this nature have been implemented with transmitter output power from about 100 mW to about 15 Watts. Even if a practical system is limited to 1% efficiency, the amount of power transferable to the implanted device while coupled to the power transmitter can be substantial (relative to the power budget of the typical implanted device). Such inductive power coupling links also have been designed to accommodate two-way or bi-directional communication between the implant and the external device.

Because of the energy/power transfer and communications link capabilities of inductive coupling, it can be used to provide power to multiple devices simultaneously, provide communications with multiple devices simultaneously and provide communications between multiple implantable devices.

A basic example of inductive coupling can be found in U.S. Pat. No. 5,519,262 to Wood. The '262 patent discloses a system for power coupling independent of the position of the receiver over a surface by using a spatially-dependent phase shift in the electromagnetic field generated by the power transmitter. In addition, the '262 patent generally discloses, without specific examples, the potential use of the invention in power and communications transmission. However, the '262 patent does not disclose or claim the use of the technology to power or access data from an implantable medical device.

U.S. Pat. No. 6,083,174 to Brehmeier-Flick et al. discloses an implantable sensor and two telemetry units – one implanted with the sensor within a flexible foil and the other extracorporeal. Although the '174 patent discloses the implanted telemetry unit as being adapted to receive a conductive power transmission from the extracorporeal telemetry unit and to transmit data to that unit, the patent explicitly disclaims the need for an implanted battery. Therefore, the invention described in the '174 patent is incapable of recharging an energy storage device implanted with the

medical device. In addition, although the '174 patent describes the use of a personal computer to capture and analyze sensed patient data, it does not disclose the use of a computer network to analyze and correlate sensed patient data from a population of patients.

U.S. Pat. No. 6,240,318 to Phillips discloses a transcutaneous energy transmission system (TETS) to provide power for any kind of implantable device requiring a source of DC power operation. The implantable device may be a mechanical circulatory support system, a left ventricular device, a muscle stimulator, vision prosthesis, audio prosthesis or other implantable device requiring DC electrical power operation. The TETS system is also adapted to recharge an implantable battery. However, the '318 patent is limited to powering devices and is not adapted to communicate patient data to external diagnostic or analytical devices.

U.S. Pat. No. 6,345,203 to Mueller, et al. discloses the use of Magnetic Vector Steering and Half-Cycle Amplitude Modulation to enhance the powering and control of multiple, arbitrarily oriented implant devices. These techniques, according to the patent, enable arbitrarily oriented implants to receive power and command, programming, and control information in a manner that preserves battery life and transmission time while reducing overall implant device bulk. More specifically, the invention of '203 patent is suitable for high-bandwidth (>1 Mbits/sec) biotelemetry that requires large amounts of energy to power the implant. Consequently, the patent suggests alternative or supplemental power sources, such as Inductive Power Transfer. In addition, the preferred use of the invention of the '203 patent is in biomedical implants placed in regions of interest about the heart of a patient. However, the '203 patent does not disclose or claim the use of induction technology to automatically recharge the battery of an implantable medical device and provide intercommunications capability with the device in proximity to an electromagnetic transmission source.

In contrast, U.S. Pat. No. 6,358,281 to Berrang, et al. discloses a cochlear device, which can be implanted, that uses an external, mechanically held, head-mounted device containing an external coil inductively coupled to a receiving coil to periodically recharge the implanted battery of the device. The external and implanted coils also can

be used as a communications link to program the implanted electronics of the device. However, the device disclosed in the '281 patent is limited to a cochlear prosthesis and is not for use beyond this limited application. In addition, the inductive coil of the implant is only configured "for receiving" data from an external means. The patent does not disclose uploading data from the implant to an analytical device or network.

Thus, for these and other reasons, there is a need for an automatic system that inductively transmits energy to an implantable medical device to power or recharge the battery of the device and fully communicate with the device or a network of such devices to improve individual patient care or the care of populations of patients. The system further eliminates the need to attach or carry an external device to enable power transmission and intercommunication.

Summary

According to one aspect of the invention, there is provided a system and method for automatically powering and communicating with an implantable medical device through an inductive transfer link, thereby providing means to periodically provide energy to the implantable medical device (or devices) to either power its immediate operation or to recharge an energy storage device (e.g., a battery) contained in the implant. In addition to the transmission of power, a transfer link can be established to enable data communication with the device or a network comprising multiple devices. For example, the inductive link may power intracorporeal ultrasound transmitters and receivers for data communication between multiple implantable devices. In either powering or communications modes, the transfer link is controlled or regulated. As used herein, a "clinician" can be a physician, physician assistant (PA), nurse, medical technologist, or any other patient health care provider.

Without any action on the patient's part, the implantable device receives the transmitted energy to power its immediate operation or recharge its battery. In addition to energy transfer, a bedside inductive system may mediate data communications through modulation on the inductive link itself or through independent (i.e., RF) means. In this way, the implantable medical device may communicate with an analytical device

or programmer to automatically monitor or upload biometric data, or program the device without discharging the battery while performing those tasks. In this embodiment, the implantable medical device is adapted to electronically store biometric data.

In another embodiment, the system may be a component of a larger network of implantable devices that allow centralized or nodal monitoring of the health status or condition of a population of patients. Inter-device communication or data transfer between implanted devices may be mediated through the inductively coupled external device or directly with another device.

The disclosure herein may apply to any type of implantable device whose operation may be limited by constrained power resources. In a preferred embodiment, the system includes a transmission module comprising at least one energizable coil mounted near a patient's bed, either in a bedside monitoring device (for example the Advanced Patient Management ("APM") bedside repeater) or, if necessary to get sufficient power coupling, under the patient's mattress or mattress pad. As known to those of skill in the art, a repeater comprises a system and device that electronically collects information from an implantable medical device and transmits that information to a centralized computer network or server for analysis. This embodiment also contemplates a complementary implantable medical device comprising at least one energizable coil to inductively link or couple with the transmission module. The system as described herein potentially removes or greatly relaxes a significant constraint in the design of implantable devices – that of power consumption.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. Those skilled in the art will readily recognize various modifications and changes that may be made to the present system without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present system, which is set forth in the following claims.

Brief Description of the Drawings

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

Figure **1** is a schematic/block diagram illustrating generally, among other things, a system for automatically establishing a powering and communications link with an implantable medical device using an inductive and/or telemetric couple.

Figure **2** is a schematic/block diagram illustrating generally, among other things, an embodiment of the coils of the system to electromagnetically couple and link an extracorporeal device with an implantable medical device.

Figure **3** is a schematic/block diagram illustrating generally, among other things, another embodiment of a system with an implantable medical device in communication with an extracorporeal analytical device or programmer to automatically monitor or upload biometric data or program the device without discharging the battery.

Figure **4** is a schematic/block diagram illustrating generally, among other things, the system as a component of a larger network of implantable devices.

Figure **5** is a schematic/block diagram illustrating generally, among other things, an embodiment of the system as a component of an Advanced Patient Management system.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration specific embodiments or examples. These embodiments may be combined, other embodiments may be utilized, and structural, logical, and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

The disclosure herein may apply to any type of implantable device whose operation may be limited by constrained power resources. This disclosure certainly applies to traditional cardiac rhythm management devices, but also to other types of implantable devices. It may enable development of extremely small, minimally invasive implantable (potentially injectable) sensing devices distributed throughout the human body, which could communicate wirelessly with one another and/or with a traditional cardiac rhythm management device to provide more complete diagnostic or analytical capabilities. For example, Muscle Sympathetic Nerve Activity (MSNA) may be measured with an injectable, microelectrode-sensing device.

After a simple initial setup procedure, the system is fully automatic for the patient. The system comprises a coil or set of coils to be mounted or installed on or near the bed of the patient. These coils are energized by a resonant circuit to generate an electromagnetic field in the vicinity of the bedside. The implanted device includes a complementary receiving coil circuit tuned to the same frequency as the transmitting coil(s), and a circuit to convert and store the received energy (e.g., a rectifying circuit). Without any action on the patient's part, the implantable device receives the transmitted energy to power its immediate operation or to recharge its energy storage device, thereby extending its longevity, potentially indefinitely.

Since there are few, if any practical constraints on the amount of power available to the transmitter (it could be plugged into a wall socket), the only practical limitations on the radiated power may be those related to patient safety and electromagnetic compatibility. Thus, in the absence of concern about prolonged exposure to the electromagnetic field, the relatively low achievable transmission energy efficiency may not be of great concern.

The system as described herein potentially removes or greatly relaxes a significant constraint in the design of implantable devices – that of power consumption. With this relaxed constraint, designers would have added freedom to:

- Increase the longevity of implanted devices;
- Reduce the size of implanted devices;
- Increase the power budget of implanted devices to enable;
    - Increased processing power;

    - Increased data storage;
    - Increased sensing abilities; and
    - Increased therapy abilities;
- Communicate with implanted sensors distributed throughout the body to enable;
    - Improved diagnostic abilities, especially in an APM environment;
    - Improved therapeutic abilities; or
    - Any combination of the above.

Figure **1** is a schematic/block diagram illustrating generally, among other things, a system **100** for automatically establishing a powering and communications link with an implantable medical device **101,** said system comprising a transmission module **102** for establishing and controlling an inductively coupled link **103** adapted to power and communicate with an implantable medical device **101**. Such a medical device **101, 101a** may include a traditional cardiac rhythm management device ("CRM"), like a pacemaker or implantable defibrillator, but may also include other implantable devices adapted to monitor and sense other biometric parameters such as electroencephalograph ("EEG") impulses, electromyography or electrical muscle measurement ("EMG"), MSNA, thoracic pressure, hemodynamic pressure other nerve conduction parameters, and various sleep parameters and positions. For example, traditional sleep clinic sensors for measuring EEG, EMG, and electrooculograph ("EOG") may need to operate only while a patient **104** is lying in bed, which is when the power source described herein could be available to the patient **104**.

As shown in Figure **2**, the disclosure herein contemplates that energizable coils **201, 202** are mounted near the patient's **104** bed, either in transmission module **102** comprising a bedside monitor device **102a** (for example the APM bedside repeater) or, if necessary to get sufficient power coupling, under the patient's **104** mattress or mattress pad. In this configuration, the system **100** comprises a loosely coupled inductive power link **103a**. When the patient **104** lies in bed, the coils in the implanted device(s) receive the radiated power and use it to power the device's **101, 101a** immediate and/or continuing operation. Preferably, the system automatically

establishes the inductive link **103a** whenever the patient **104** is in or near a bed adapted with energizable coils, or at night while the patient **104** is in or near such a bed.

Figure **2** also illustrates a method of using a system **100** to establish an inductive link an implantable medical device **101a** and a transmission module **102**. The method comprises the steps of bringing the implantable medical device **101 may** within operational proximity to the transmission module **102** to automatically establish a loosely coupled inductive link **103a** between the device **101a** and the module **102**. Once established, the inductive link is regulated to transfer power from the transmission module **102** to the implantable medical device **101a** and/or transfer data between the module **102** and the implantable medical device **101a**. The method may further comprise the step of recharging an energy storage device of the implantable medical device **101a**.

In addition to energy transfer, a bedside inductive system may mediate communications through modulation of the inductive link itself or through independent (i.e., RF) means. Communication may be bi-directional to allow upload and download of data. As shown in Figure **3**, the inductive system **100** is adapted to allow an implantable medical device **101, 101a** to communicate **300** with a transmission module that may be further adapted to comprise an analytical device or programmer **102a** to automatically monitor, download or upload biometric data and/or program the implantable device **101, 101a** without discharging the device's battery in addition to controlling the link **103, 103a, 300** between the transmission module **102a** and the implantable medical device **101, 101a**. The independent communications means may include a Bluetooth® RF transmitter and receiver **301** as a component of the device **101** and programmer **102a** that derives power from the inductive link **103, 103a**.

The system may also be a component of a larger network **400** of implantable devices that allow centralized or nodal monitoring of the health status or condition of a population of patients **401**. Figure **4** illustrates an embodiment adapted to communicate **402** with multiple implantable devices **101a, 101b, 101c** and other medical devices that may be implanted within the same patient or other patients and that may be enabled and/or mediated through an inductive link **103a**. Inter-device communication **403**

between implanted devices may be mediated through an inductively coupled external device **102, 404** or direct device-to-device communication may be enabled by the additional power/energy available to the implanted device through the inductive power coupling of the internal and external devices. The inductive link may be further adapted to power intra-corporeal ultrasound transmitters and receivers **405** for communication between multiple, implantable devices. Intercommunication **403** between multiple implantable sensor/therapy modules or devices **101a, 101b, 101c** mediated through transmission modules **102, 404** may be further adapted to electronically communicate on a network to share data **406** with another external device like an APM system **407** accessible by the patient and/or a clinician. APM provides more accurate real-time adaptive therapy based on more comprehensive information about the status of a patient.

As further shown in figure **4**, a method of using the system may include establishing an inductive link **103a** to power data transfer **402** between a plurality of implantable medical devices **101a**, **101b** and **101c**. It is further contemplated the method includes the step of the transmission module **404** analyzing the data **402** transferred from implantable medical devices **101a**, **101b**, **101c**, said data comprising biometric parameters. The method may also include the step of powering data transfer **406** between an implantable medical device **101c** and an APM system **407**. Such communication **406** can be mediated directly with the APM **407** or through an electronic connection **408** with transmission module **404**.

Figure **5** illustrates generally, among other things, an embodiment comprising an APM that not only provides the system **100, 500** with power advantages, but also is adapted to communicate with a larger network of implantable devices with APM capabilities to allow the clinician to monitor and control a population of patients **401**. APM is a system that helps patients, their physicians and their families to better monitor, predict and manage chronic diseases. APM is particularly useful in maintaining long-term data continuity and combining information from medical devices, including the system for powering and communicating with an implantable medical device **101a** disclosed herein, with patient data from other medical databases.

In the embodiment shown in Figure **5**, the APM system **500** comprises three primary components: 1) a transmission module, **102, 102a**; 2) an implantable medical device **101a**, including at least one sensor adapted to monitor physiological functions; 3) a data management system **501** comprising patient **501a, 501b** and medical **501c, 501d** databases; and 4) an analytical engine **502** that analyzes data from the data management module. APM is designed to support physicians and other clinicians in using a variety of different devices, patient-specific and non-specific data, along with medication therapy, to provide the best possible care to patients.

The various embodiments described above are provided by way of illustration only and should not be construed to limit the invention. The above-described embodiments may be used in combination with each other. Those skilled in the art will readily recognize various modifications and changes that may be made to the present invention without following the example embodiments and applications illustrated and described herein, and without departing from the true spirit and scope of the present invention, which is set forth in the following claims and their equivalents. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein."